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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/573,973

02/22/2007

Keiji Sakamoto

P29617

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7055 7590 07/01/2008
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EXAMINER

HENRY, MICHAEL C

ART UNIT

PAPER NUMBER

1623

NOTIFICATION DATE

DELIVERY MODE

07/01/2008

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

gbpatent@gbpatent.com
pto@gbpatent.com

Office Action Summary	Application No. 10/573,973	Applicant(s) SAKAMOTO ET AL.	
	Examiner MICHAEL C. HENRY	Art Unit 1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 March 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The amendment filed 03/07/08 affects the application, 10/573,973 as follows:

1. Claim 6 has been amended. The rejections made under 35 U.S.C. 102 and 103(a) are maintained.
2. The responsive to applicants' arguments is contained herein below.

Claims 1-10 are pending in application

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 6 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 6 recites the phrase "to the composition". However, the claim is indefinite since it is unclear to which composition is the compound represented by the general formula (v) added.

Claim Rejections - 35 USC § 102

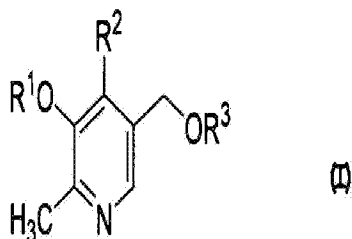
The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 5, 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Trumbo et al. (Journal of Nutrition (1988), 118 (2), 170-5).

In claim 1, applicant claims a compound represented by the following general formula (I) or a salt thereof:

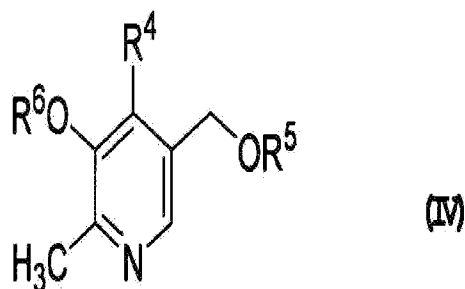


wherein R¹ represents a glycosyl group, a phosphate group, or a cyclic phosphate group bound to R²; R² represents -CH₂OH, -CHO, -CH₂NH₂, -CH₂-amino acid residue, or -CH₂-OPO₂H; and R³ represents hydrogen atom, or -PO₃H₂. Trumbo et al. disclose applicant's compound represented by the general formula (I) wherein R¹ represents a glycosyl group; R² represents -CH₂OH; and R³ represents hydrogen atom (see abstract). Trumbo et al.'s compound has a Cas # of 72551-78-1 (see abstract).

Claim 2 is drawn to the compound or a salt thereof according to claim 1, which is selected from the group consisting of pyridoxine 3- β -glucoside, pyridoxine 3- α -glucoside, pyridoxamine 3- β -glucoside, pyridoxamine 3- α -glucoside, pyridoxal 3- β -glucoside, pyridoxal 3- α -glucoside, pyridoxine 3- β -galactoside, pyridoxine 3- α -galactoside, N-(4-pyridoxylmethylene)-L-serine 3- β -glucoside, N-(4-pyridoxylmethylene)-L-serine 3- α -glucoside, pyridoxine 3-phosphate, pyridoxine 3,4'-cyclic phosphate, and N-(4-pyridoxylmethylene)-L-serine 3-phosphate, or a salt thereof. Trumbo et al. disclose applicant's compound, pyridoxine 3- β -glucoside (see abstract). Trumbo et al.'s compound has a Cas # of 72551-78-1 (see abstract).

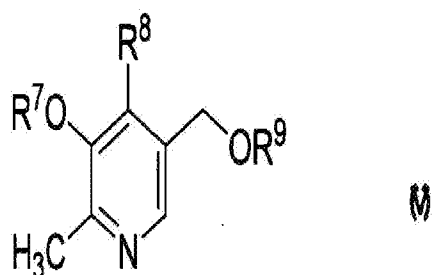
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Claim 3 is drawn to a compound represented by the following general formula (IV) or a salt thereof:



wherein R^4 represents $-CH_2OH$, $-CHO$, or $-CH_2NH_2$, or represents $-CH_2OH$, $-CHO$, or $-CH_2NH_2$ protected with a protective group; R^5 represents hydrogen atom, a protective group of hydroxyl group, a phosphate group, or a protected phosphate group; and R^6 represents a glycosyl group which may have a protective group, or a phosphate group which may have a protective group. Trumbo et al. disclose applicant's compound represented by the general formula (IV) wherein R^6 represents a glycosyl group; R^4 represents $-CH_2OH$; and R^5 represents hydrogen atom (see abstract). Trumbo et al.'s compound has a Cas # of 72551-78-1 (see abstract).

In claim 5, applicant claims a composition for a cosmetic, a medicament, a foodstuff, and/or a feed comprising a compound represented by the following general formula (V) or a salt thereof:



wherein R^7 represents a glycosyl group, a phosphate group, a sulfate group, or a cyclic phosphate

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group bound to R⁸; R⁸ represents -CH₂OH, -CHO, -CH₂NH₂, -CH₂-amino acid residue, or -CH₂-OPO₂H; and R₉ represents hydrogen atom, or -PO₃H₂. Trumbo et al. disclose applicant's composition or compound represented by the general formula (V) wherein R⁷ represents a glycosyl group; R⁸ represents -CH₂OH; and R⁹ represents hydrogen atom (see abstract). Trumbo et al.'s compound has a Cas # of 72551-78-1 (see abstract). It should be noted that it is well settled that "intended use" of a composition or product, e.g., for a cosmetic or a medicament, does not further limit claims drawn to a composition or product. See, e.g., *Ex parte Marsham*, 2 USPQ2d 1647 (1987) and *In re Hack* 114, USPQ 161.

In claim 8, applicant claims the composition for cosmetics according to claim 5, which is a whitening agent, an anti-aging agent, and/or an agent for suppressing wrinkle formation by exposure to ultraviolet light. Trumbo et al. disclose applicant's compound represented by the general formula (IV) wherein R⁶ represents a glycosyl group; R⁴ represents -CH₂OH; and R⁵ represents hydrogen atom (see abstract). Trumbo et al.'s compound has a Cas # of 72551-78-1 (see abstract). It should be noted that it is well settled that "intended use" of a composition or product, e.g., for a cosmetic or a medicament, does not further limit claims drawn to a composition or product. See, e.g., *Ex parte Marsham*, 2 USPQ2d 1647 (1987) and *In re Hack* 114, USPQ 161. It should be noted that Trumbo et al.'s compound or composition is the same as applicant's and therefore it should inherently possess the same property of being a whitening agent or an anti-aging agent.

Claim Rejections - 35 USC § 103

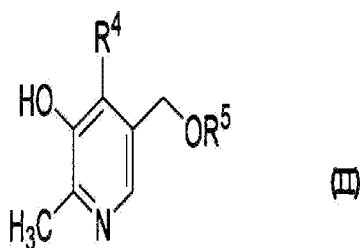
The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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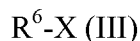
(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ogata et al. (The Journal of Vitaminology 15, 160-166 (1969)) in combination with Trumbo et al. (Journal of Nutrition (1988), 118 (2), 170-5).

In claim 4, applicant claims a method for preparing a compound represented by the general formula (I) or a salt thereof according to claim 1, which comprises the step of reacting a compound represented by the following general formula (II) or a salt thereof:



wherein R^4 represents $-CH_2OH$, $-CHO$, or $-CH_2NH_2$, or represents $-CH_2OH$, $-CHO$, or $-CH_2NH_2$ protected with a protective group; and R^5 represents hydrogen atom, a protective group of hydroxyl group, a phosphate group, or a protected phosphate group, with a compound represented by the following general formula (III):



wherein R^6 represents a glycosyl group which may have a protective group, and X represents a leaving group, to obtain a compound represented by the general formula (IV) according to claim 3, and if necessary, the step of deprotecting the compound represented by the aforementioned general formula (IV).

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Ogata et al. disclose a method for preparing pyridoxine 5'- α -D-glycoside comprising reacting α^4 , 3-O-Isopropylidene pyridoxine (wherein the 3 and 4 positions hydroxy groups are protected and the 5 position hydroxyl group is unprotected) with 2,3,4,6-tetra-O-benzyl D-glucopyranosyl chloride (a compound of general formula (III): R^6-X (III)) (see abstract and see also page 163, section 4).

The difference between applicants claimed method and the method of Ogata et al. is the type of pyridoxine used and the fact that Ogata et al. prepares pyridoxine 5'- α -D-glycoside.

Trumbo et al. disclose applicant's compound represented by the general formula (I) wherein R^1 represents a glycosyl group; R^2 represents $-CH_2OH$; and R^3 represents hydrogen atom (see abstract). Trumbo et al.'s compound has a Cas # of 72551-78-1 (see abstract). Thus, one having ordinary skill in the art would have been motivated to use Ogata et al.'s method to prepare Trumbo et al.'s compound and to react a different pyridoxine such as an isopropylidene pyridoxine (wherein the 4 and 5 positions hydroxy groups are protected and the 3 position hydroxy groups are unprotected) with 2,3,4,6-tetra-O-benzyl D-glucopyranosyl chloride (a compound of general formula (III): R^6-X (III))).

It would have been obvious to one having ordinary skill in the art, at the time the claimed invention was made to use the method of Ogata et al.'s to prepare Trumbo et al.'s compound and to react a different pyridoxine such as an Isopropylidene pyridoxine (wherein the 4 and 5 positions hydroxy groups are protected and the 3 position hydroxy groups are unprotected) with 2,3,4,6-tetra-O-benzyl D-glucopyranosyl chloride (a compound of general formula (III): R^6-X (III))) in order to use it as a vitamin.

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One having ordinary skill in the art would have been motivated, in view of Ogata et al. and Trumbo et al., to use the method of Ogata et al.'s to prepare Trumbo et al.'s compound and to react a different pyridoxine such as an isopropylidene pyridoxine (wherein the 4 and 5 positions hydroxy groups are protected and the 3 position hydroxy groups are unprotected) with 2,3,4,6-tetra-O-benzyl D-glucofuranosyl chloride (a compound of general formula (III): R^6-X (III))) in order to use it as a vitamin.

Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Trumbo et al. (Journal of Nutrition (1988), 118 (2), 170-5).

In claim 7, applicant claims a composition for a cosmetic, a medicament, foodstuff, and/or a feed containing a compound represented by the general formula (V) or a salt thereof mentioned in claim 5 and at least one kind of vitamin, wherein stability of the vitamin is improved.

Trumbo et al. disclose the pyridoxine glucoside, 5'-O-(.beta.-D-glucofuranosyl) pyridoxine (also called .beta.-D-Glucofuranoside, 4,5-bis(hydroxymethyl)-2-methyl-3-pyridinyl) (see abstract). Trumbo et al.'s compound has a Cas # of 72551-78-1 (see abstract). Trumbo et al. disclose that 5'-O-(.beta.-D-glucofuranosyl) pyridoxine can be utilized as vitamin B6 (see abstract).

The difference between applicants claimed composition and the composition of Trumbo et al. is that applicant's composition also contains another vitamin.

It would have been obvious to one having ordinary skill in the art, at the time the claimed invention was made, to prepare a composition comprising a combination of Trumbo et al.'s

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compound and another vitamin which have the same utility in order to use it in nutritive, food stuff or a medicament.

One having ordinary skill in the art would have been motivated, to prepare a composition comprising a combination of Trumbo et al.'s compound and another vitamin which have the same utility in order to use it in a nutritive, a food stuff or a medicament.

Claims 9, 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over PENTPHARM JAPAN KK (JP 20002-265316, Abstract Only)) in combination with Trumbo et al. (Journal of Nutrition (1988), 118 (2), 170-5).

In claim 9, applicant claims a composition comprising (A) a compound represented by the general formula (V) according to claim 5, and (B) one or more kinds of substances selected from the group consisting of a whitening agent, an antioxidant, an antiphlogistic, a circulation accelerator, a cell activation agent, and an ultraviolet absorber, which is used as a whitening agent, an anti-aging agent, and/or an agent for suppressing wrinkle formation by exposure to ultraviolet light. Claim 10 is drawn to a whitening agent containing (A) a compound represented by the general formula (V) mentioned in claim 5, and (B) arbutin.

PENTPHARM JAPAN KK discloses a composition or skin care preparation having prevention effect on chapped skin, ameliorating effect on chapped skin, etc., excellent prevention effect on aging by preventing loss of luster. PENTPHARM JAPAN KK composition or skin care preparation is characterized in that the skin care preparation comprises pyridoxine- α -D-glucoside and may contain 0.05-20.0 wt.% of pyridoxine- α -D-glucoside and 0.05-10.0 wt.% of α -arbutin (see abstract). It should be noted that α -arbutin is a skin whitening or lightening agent.

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This suggest that pyridoxine glucosides in combination with the arbutin the skin whitening or lightening agent can be used to treat skin conditions or aging.

The difference between applicants claimed composition and PENTPHARM JAPAN KK's composition is the type of pyridoxine glucoside used.

Trumbo et al. disclose the pyridoxine glucoside, 5'-O-(.beta.-D-glucopyranosyl) pyridoxine (also called .beta.-D-Glucopyranoside, 4,5-bis(hydroxymethyl)-2-methyl-3-pyridinyl) (see abstract). Trumbo et al.'s compound has a Cas # of 72551-78-1 (see abstract).

It would have been obvious to one having ordinary skill in the art, at the time the claimed invention was made, in view of PENTPHARM JAPAN KK and Trumbo et al. to prepare a composition or skin care preparation comprising a pyridoxine glucoside such as Trumbo et al.'s 5'-O-(.beta.-D-glucopyranosyl) pyridoxine and α -arbutin in order to use it to treat skin conditions such as chapped or aging skin.

One having ordinary skill in the art would have been motivated, in view of PENTPHARM JAPAN KK and Trumbo et al. to prepare a composition or skin care preparation comprising a pyridoxine glucoside such as Trumbo et al.'s 5'-O-(.beta.-D-glucopyranosyl) pyridoxine and α -arbutin in order to use it to treat skin conditions such as chapped or aging skin.

Response to Arguments

Applicant's arguments with respect to claims 1-10 have been considered but are not found convincing.

The applicant argues that the compound in Trumbo identified as CAS No. 72551-78-1 was falsely identified and is in fact 5'-O-(13-D-Glucopyranosyl)pyridoxine (CAS No. 63245-12-5). The two compounds are structural isomers and differ in the position of the glycosyl group.

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However, the compound claimed by applicant of the given general formula has the same structure as the compound disclosed by Trumbo et al. with a CAS NO. 72551-78-1 (see above rejection). In addition, applicant's arguments as to whether or not the compound with CAS NO. 72551-78-1 is actually the compound with a CAS No. 63245-12-5 is irrelevant, since the compound was already known or disclosed before applicant's claimed invention. Furthermore, there are other references other than Trumbo et al.'s reference in which the compound CAS NO. 72551-78-1 (applicant's claimed compound) is disclosed. In this regard, the examiner presents two of the said references, Exhibit A (Tadera et al.; Journal of Nutritional Science and Vitaminology (1979), 25(4), 347-50) and Exhibit B (Gilbert et al.; Journal of Nutrition (1992), 122(4), 1029-35) wherein the structure of applicant's compound is disclosed (see structure CAS NO. 72551-78-1). This implies that regardless of applicant's arguments the compound was already known, disclosed or published before applicant's claimed invention was made.

The applicant argues that Trumbo does not disclose analytical data to reveal the structure of the pyridoxine glycoside. However, Trumbo et al. disclose applicant's compound and analytical data is not required to reveal the structure of said compound.

The applicant argues that Gregory, J.F. III., who is a co-author of Trumbo, reports in J. Agric. Food Chem., vol. 35 (1987), pp. 75-82, a copy of which is provided for the Examiner's convenience, further studies of pyridoxine glycosides. In this publication, Gregory also reports the above synthesis and includes NMR data confirming the above-shown structure of CAS No. 63245-12-5. An additional publication by Gregory in Methods of Enzymology, vol. 280 (1997) (Vitamins and Coenzyme Part J), pp. 58-71, a copy of which is provided as well, show the same data. However the reference used to make the above rejection is not the

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aforementioned references. Furthermore, the compound claimed by applicant of the given general formula has the same structure as the compound disclose by Trumbo et al. with a CAS NO. 72551-78-1 (see above rejection). In addition, applicant's arguments as to whether or not the compound with CAS NO. 72551-78-1 is actually the compound with a CAS No. 63245-12-5 is irrelevant, since the compound was already known, disclosed or published before applicant's claimed invention. Furthermore, there are other references other than Trumbo et al.'s reference in which the compound CAS NO. 72551-78-1 (applicant's claimed compound) is disclosed. In this regard, the examiner presents two of the said references, Exhibit A (Tadera et al; Journal of Nutritional Science and Vitaminology (1979), 25(4), 347-50) and Exhibit B (Gilbert et al.; Journal of Nutrition (1992), 122(4), 1029-35) wherein the structure of applicant's compound is disclosed (see structure CAS NO. 72551-78-1). Moreover, regardless of applicant's arguments the compound was already known, disclosed or published before applicant's claimed invention.

The applicant argues that Furthermore, Applicants respectfully submit that the Pyridoxine 5'- β -D-glucoside, i.e., the compound discussed in Trumbo is identified in CAS as No. 63245-12-5. This fact shows that CAS No. 72551-78-1 was erroneously listed in the Chemical Abstract of Trumbo and should disclose CAS No. 63245-12-5. As further evidence for the structure and the identity of compound 63245-12-5, Applicants submit herewith copies of Agric. Biol. Chem., vol. 41 (1977), pp. 1061-1067 and Bull. Res. Inst. Bioresour. Okayama Univ., vol. 5 (1980), pp. 107-120. However the reference used to make the above rejection is not the as the aforementioned references. Furthermore, the compound claimed by applicant of the given general formula has the same structure as the compound disclose by Trumbo et al. with a CAS NO. 72551-78-1 (see above rejection). In addition, applicant's argument as to whether or not the compound with CAS

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NO. 72551-78-1 is actually the compound with a CAS No. 63245-12-5 is irrelevant, since the compound was already known or disclosed before applicant's claimed invention. Furthermore, there are other references other than Trumbo et al.'s reference in which the compound CAS NO. 72551-78-1 (applicant's claimed compound) is disclosed. In this regard, the examiner presents two of the said references, Exhibit A (Tadera et al; Journal of Nutritional Science and Vitaminology (1979), 25(4), 347-50) and Exhibit B (Gilbert et al.; Journal of Nutrition (1992), 122(4), 1029-35) wherein the structure of applicant's compound is disclosed (see structure CAS NO. 72551-78-1). Moreover, regardless of applicant's arguments the compound was already known, disclosed or published before the time applicant's claimed invention was made.

The applicant argues that the compounds of the present invention carry the glycosyl group only as R¹ in the 3-position of the pyridoxine ring, which is structurally distinguished from the compound disclosed in Trumbo. However, the compound claimed by applicant of the given general formula has the same structure as the compound disclose by Trumbo et al. with a CAS NO. 72551-78-1 (see above rejection and applicant's claims). In addition, applicant's argument as to whether or not the compound with CAS NO. 72551-78-1 is actually the compound with a CAS No. 63245-12-5 is irrelevant, since the compound was already known, disclosed or published before the time applicant's claimed invention was made.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after

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the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Henry whose telephone number is 571-272-0652. The examiner can normally be reached on 8.30am-5pm; Mon-Fri. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia A. Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Michael C. Henry

June 22, 2008.

/Shaojia Anna Jiang, Ph.D./

Supervisory Patent Examiner, Art Unit 1623

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